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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/801,379	03/15/2004	Iddys D. Figueroa	200401492-1	3171

22879 7590 06/05/2008

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EXAMINER	
CAMERON, ERMA C	
ART UNIT	**PAPER NUMBER**
1792	

NOTIFICATION DATE	DELIVERY MODE
06/05/2008	ELECTRONIC

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte IDDYS D. FIGUEROA, VANESSA I. CHINEA,
ORLANDO RUIZ, DOUGLAS A. SEXTON,
WINTHROP D. CHILDERS, JAMES W. AYRES,
JOHN STEPHEN DUNFIELD

Appeal 2008-2802
Application 10/801,379
Technology Center 1700

Decided: June 3, 2008

Before EDWARD C. KIMLIN, BRADLEY R. GARRIS, and
LINDA M. GAUDETTE, *Administrative Patent Judges*.

KIMLIN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal from the final rejection of claims 1-7 and 25-29. Claim 1 is illustrative:

1. A method of controlling a dissolution rate of a bioactive agent, the

method comprising:

identifying a target dissolution rate;

selecting a desired dot topography corresponding to the target dissolution rate; and

applying a bioactive agent to a delivery substrate to form dots having the desired dot topography on the delivery substrate.

The Examiner relies upon the following references as evidence of obviousness:

Voss	4,322,449	Mar. 30, 1982
Voges	5,894,841	Apr. 20, 1999

Appellants' claimed invention is directed to a method of controlling a dissolution rate of a bioactive agent. The method entails identifying a target dissolution rate, and selecting a topography for deposited dots which contain the bioactive agent that corresponds to the target dissolution rate. According to Appellants' Specification, "dot topography is used to refer to surface detail of the dot" (p. 18, ll. 21-22). The Specification further states that "[a] highly textured surface can provide much more surface area than a smooth surface [and] [t]he amount of topographic surface area typically directly corresponds to the probability that the dot will dissolve" (p. 18, ll. 23-26).

Appealed claims 1, 2, 4-7 and 25-29 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Voss. Claim 3 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Voss in view of Voges.

We have thoroughly reviewed each of Appellants' arguments for patentability. However, we are in complete agreement with the Examiner that the claimed subject matter would have been obvious to one of ordinary skill in the art within the meaning of § 103 in view of the applied prior art.

Accordingly, we will sustain the Examiner's rejections for the reasons set forth in the Answer, and we add the following primarily for emphasis.

There is no dispute that Voss, like Appellants, discloses a method of applying a bioactive agent to a delivery substrate in the form of dots having a desired geometrical pattern. Also, Appellants do not dispute the Examiner's factual determination that Voss discloses that the dosing of the bioactive agent in the dots may be controlled by a variety of parameters, such as the diameter of the outlet opening of the nozzle channels, the number of nozzle channels, the active substance concentration of the solution or suspension comprising the bioactive agent, and the number of dots of active substance per pharmaceutical carrier, etc. (see col. 4, lines 13 et seq.). It is Appellants' contention that the dissolution rate of the bioactive agent is distinct from the dosage of the agent. Appellants maintain that Voss "is silent with respect to the selection of a target dissolution rate, and is silent with respect to what characteristics of dot topography may confer a greater or lesser dissolution rate on applied pharmaceuticals" (p. 6 of Brief, last para.).

Although Appellants are correct in stating that Voss is silent with respect to selecting a target dissolution rate, we are convinced that such silence does not militate against the obviousness of selecting a desired dissolution rate to one of ordinary skill in the art. Appellants have not refuted the Examiner's finding that medical professionals, such as doctors, pharmacists, etc., were well aware at the time of filing the present application that the safe and effective administration of a drug to a patient requires the delivery of a precise dosage of the drug at an acceptable rate. We also fully concur with the Examiner that one of ordinary skill in the art

"would have been aware that a too-rapid dissolution rate could lead to an over-dose, whereas a too-slow dissolution rate could lead to infective treatment levels" (p. 4 of Answer, last para.). Hence, Voss' silence notwithstanding, we agree with the Examiner that the claimed step of "identifying a target dissolution rate" would have been obvious to one of ordinary skill in the art.

As for the selection of the dot topography, Appellants have not refuted the Examiner's finding that "[o]ne of ordinary skill in the art would have been well aware of the effects of surface area on dissolution rate, for example, that a plurality of small, thin dots would dissolve faster than a thick, large dot of the same total volume" (p. 5 of Answer, second para.). Also, it was notoriously well known that the rougher the surface area of a substrate, particle, dot, etc., the greater the surface area that is exposed to the surrounding environment. Accordingly, we concur with the Examiner that it would have been obvious to one of ordinary skill in the art that a dot comprising a bioactive agent having a textured or rough surface will have a greater dissolution rate than a dot having a smooth surface which presents a smaller surface area. Manifestly, the topography or surface texture of a dot is a result effective variable which determines the dissolution rate of the bioactive agent within the dot, and it is well settled that determining the optimum value of a result effective variable is a matter of obviousness for one of ordinary in the art. *In re Boesch*, 617 F.2d 272, 276 (CCPA 1980). Consequently, we find no error in the Examiner's rationale that it would have been obvious for one of ordinary skill in the art to control the deposition parameters discussed by Voss to attain the optimum dot topography and, therefore, dissolution rate.

Moreover, we note that Appellants point to no particular methodology for depositing the claimed dots that is distinct from the process fairly taught by Voss such that a distinct dot topography is achieved. Significantly, appealed claim 1 recites no particular dissolution rate or dot topography, and Appellants have presented no argument, let alone supporting objective evidence, that dot topographies within the scope of the appealed claims are different than the topographies of the dots produced by Voss. To be sure, the bioactive agent-containing dots of Voss have a topography that is necessarily associated with the dissolution rate of the agent.

Concerning claim 27, since it was known in the art that bioactive agents may have many crystal forms, we agree with the Examiner that it would have been obvious for one of ordinary skill in the art to employ routine experimentation to determine the particular crystal form of bioactive agents which provides the desired dissolution rate. Claim 27 on appeal fails to recite any particular crystal form.

Regarding separately rejected claim 3, we concur with the Examiner that Voges evidences the obviousness of employing either a piezoelectric or a thermal type of ink jet printing for depositing the bioactive agent-containing drops of Voss. Appellants' argument that "the modification would destroy the utility of the Voges dispenser for inhalation therapy" misses the thrust of the Examiner's rejection (see p. 11 of Brief, second para.). The Examiner's conclusion of obviousness is not based upon any modification of the Voges dispenser but rests upon the obvious use of alternative types of ink jet printing.

As a final point, we note that Appellants base no argument upon objective evidence of nonobviousness, such as unexpected results.

In conclusion, based on the foregoing and the reasons well-stated by the Examiner, the Examiner's decision rejecting the appealed claims is affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED

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